



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,395	05/08/1998	RONALD MATHISON	024916-006	7952

21839 7590 02/11/2002

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1653

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/051,395

Applicant(s)

MATHISON ET AL.

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9, 11, 13-15, 25 and 38-103 is/are pending in the application.
- 4a) Of the above claim(s) 13, 25, 39-49 and 64-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 7-9, 11 and 38 is/are allowed.
- 6) ☐ Claim(s) 14, 15, 38, 50-63 and 90-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 11-19-01 is hereby acknowledged. Claims 7, 14-15, 50, 52, 56, and 58 were amended and claims 90-103 were added. Claims 7-9, 11, 13-15, 25, 38-103 are pending in this application

Election/Restriction

2. Applicant arguments with regards to claims 9, 53, 55, 59, and 61 are acknowledged. These claims have been combined with claims under examination. Thus, claims 7-9, 14-15, 38, 50-63 and new claims 90-103 have been examined in the application. Claim 13, 25, 39-49, and 64-89 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The rejection of claims 7-8, 14-15, 38, 50, 52, 54, 56, 58, 60, 62-63, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn.

4. The rejection of claims 7-8 and 38, rejected under 35 U.S.C. 102(b) as being anticipated by Sloodstra et al. is hereby withdrawn.

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 14-15, 38, 50-63 and new claims 90-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment or reduction of anaphylactic reactions with the peptide FEG, does not reasonably provide enablement for any peptide corresponding to the formula R1-X1-X2-R2 for the same purpose and as directed to prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable the invention commensurate in scope with these claims for the reasons set forth in the previous office action and the reasons set forth below.

Applicants argue that Example 3 of the specification shows the prevention of an intestinal anaphylactic reaction by the peptide corresponding to SEQ. ID NO. 8. Applicants then state that this same model was used to demonstrate the activity for peptides TDIFEGG, TAIFEGG, TDAFEGG, FEGG, FEG as disclosed in Table 2 of the specification and make reference to other peptides tested that showed effectiveness in preventing anaphylactic reactions.

With respect to the anaphylactic hypotension, Applicants make reference to peptide FEG and feG in example three to demonstrate the prevention of anaphylactic hypotension. Thus, Applicants argue, contrary to *Ex parte Sudilovsky*, 21 U.S.P.Q2d 1702 (BPAI 1991) the instant application provides many examples and is not confined to broad allegation and suggestion.

6. Applicant's arguments filed 11-19-01 have been fully considered but they are not persuasive.

Applicants' specification, specifically table 2, clearly demonstrates the unpredictability associated with peptide chemistry as indicated in the previous office action. It should be noted that in Table 2, of the 10 peptides tested only three peptides showed activity greater than 40% with six of the peptides showing no activity (**emphasis added**). Thus applicants own data demonstrates that the mere fact that a peptide may correspond to the formula R1-X1-X2-R2, is not a prerequisite for activity in treating or preventing anaphylactic reactions. In fact the some of the peptides claimed in claims 51 and 57 were inactive (specifically SEQ. ID. NO. 6), according to table 2, in establishing the claimed activity. It is unclear how Applicants can claim the inhibition of anaphylactic reactions when their own specification indicates otherwise. Thus, unlike Applicants contentions, the claimed invention is similar to *Ex parte Sudilovsky* since applicants have not provided working examples to substantiate the activity for the scope of the claims. "Any disclosure regarding utility is confined to broad allegations and suggestions without substantiating working examples." Examples, where majority of the peptides were inactive, cannot be construed as substantiating working examples to demonstrate the claimed activity.

This argument also applies to the activity of reducing or preventing anaphylactic hypotension. Here Applicants have made reference to the activity through two working peptides. Given that six of the 10 peptides were inactive towards reducing or preventing an anaphylactic reaction, one could not readily predict that any peptide corresponding to the formula R1-X1-X2-R2 would be effective the treatment sought.

Further, it is unclear what examples given clearly establish the prevention anaphylactic reactions and/or prevention of anaphylactic hypotension. Table 7 in the specification indicates that the maximum inhibitory activity achieved for the most active peptides was ~60% (see page 8). The data does not demonstrate that 100% of inhibition was achieved. Prevention of a biological activity usually implies that 100%, or close to 100%, activity is inhibited. Here only 60% only inhibition activity was achieved, thus prevention was not achieved.

Rejection is maintained.

***New Grounds For Rejections
Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 90-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims correspond to an "effective derivative" of the peptide FEG. It is unclear what modification to the sequence of what additions to the sequence would yield an "effective derivative." Further it is unclear what this derivative is effective towards. The claims are indefinite.

9. Claims 7-9, 11 and 38 are allowed.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Application/Control Number: 09/051,395
Art Unit: 1653

Page 5

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta 2/1/2


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600